

My5-FU













My5-FU™ Sample Stabilizer Kit

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Key to Symbols Used

	<i>in vitro</i> Diagnostic Device		Consult Instructions for Use
	Catalog Number		Use By
	Batch Code		Temperature Limitation
	Manufacturer		Serious Health Hazards
	Flammable		Health Hazards
	Authorized Representative in Switzerland		
	Authorized Representative in the European Community		


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Intended Use

The Saladax My5-FU Sample Stabilizer Kit is intended to stabilize 5-fluorouracil in blood samples collected for analysis in the My5-FU Assay. The Sample Stabilizer Kit is intended to ensure sample integrity from draw through analysis.

Contents

The My5-FU Sample Stabilizer Kit consists of:

- My5-FU Sample Stabilizer (0.1 mL), containing 0.12 mg/mL gimeracil in a 30% methanol solution
- BD Vacutainer® Blood Transfer Device

Additional Required Equipment (not provided)

EDTA or heparin tube for collection of ≥ 2 mL of blood.

Storage and Shelf life

Store the My5-FU Sample Stabilizer Kit at ambient temperature. The My5-FU Sample Stabilizer Kit is stable until the expiration date when stored as directed.

Warnings and Precautions

For In Vitro Diagnostic Use.

Handle and dispose of sharps (needle) in accordance with applicable regulations.

Limitations of the Procedure

Sample integrity and accurate results with the My5-FU Assay are dependent upon the proper storage and use of the My5-FU Sample Stabilizer Kit as directed and good laboratory technique.

After collecting the blood and injecting the collection tube with the supplied stabilizer, **DO NOT** place the sample on ice and do not refrigerate the sample. This may result in an increase in interference from hemolysis leading to erroneous 5-FU results.

Instructions for Use

- Refer to the Saladax My5-FU Assay package insert for a complete summary and explanation of the test.
- COLLECT ≥ 2 ML OF BLOOD into an EDTA or heparin tube from a peripheral port or by venous draw.
 - DO NOT** use plasma separator tubes.
 - DO NOT** draw from the drug infusion port.
 - DO NOT** do a short draw.
- INJECT COLLECTION TUBE WITH SUPPLIED STABILIZER immediately after draw and gently invert 3 times. CENTRIFUGE SAMPLE WITHIN 24 HOURS of the draw.
 - DO NOT** place sample on ice and **DO NOT** refrigerate when using the stabilizer.
 - DO NOT** test any sample that was not treated with the stabilizer.
 - DO NOT** test any sample that was not centrifuged within 24 hours.
- CAREFULLY DRAW OFF PLASMA from the top of the tube, avoiding cell layer and transfer to a capped secondary tube. Plasma must be free of cells. Store the plasma sample at 2 - 8°C or room temperature for up to one week or freeze (at $\leq -20^{\circ}\text{C}$) if storing the sample longer.
- SAMPLE CAN BE SHIPPED AT AMBIENT TEMPERATURE. Provide the laboratory with the times of infusion start and finish.